2023 ARCS
ANNUAL CONFERENCE

6 - 8 June 2023
International Convention Centre
Darling Harbour, Sydney

CALL FOR ABSTRACTS
Conference Submission Guidelines

ARCS AUSTRALIA®

Annual Conference Program Committee (ACPC)


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2023 ARCS Annual Conference Call for Abstracts

ARCS Australia and the Annual Conference Program Committee (ACPC) wishes to invite all interested parties from industry, research institutions, healthcare consumers, government and academia involved in development through to commercialisation of therapeutics to make program submissions for the 2023 ARCS Annual Conference (6 – 8 June 2023) to be held at the International Convention Centre (ICC), Darling Harbour, Sydney.

The ACPC have highlighted priority topics within each educational theme to provide direction on content they would like to receive via the Call for Abstracts. You may submit abstracts addressing priority topics and/or topics relevant to the overall theme descriptions. Both priority topics and theme specific topics will be reviewed and considered by the ACPC. More information is located in Appendix A.

Members and non-members of ARCS are invited to make submissions in accordance with these Submission Guidelines. Submissions which include a patient or health consumer perspective are encouraged. Priority will also be given to proposals which appeal to a cross functional audience and are aligned with areas identified in these Submission Guidelines.

SUBMISSION PLANNING FORM

This will help ensure that you have all the required information available before submitting your proposal. All submissions must be submitted online by the designated deadline. Should you have questions regarding the submission process, **please contact arcs@arcs.com.au**

MAKE A SUBMISSION TODAY

Please ensure your submission is completed in compliance with the Submission Guidelines no later than **FRIDAY 28 October 2022**

REWARD AND RECOGNITION

ARCS offers reward and recognition packages for speakers and chairs who are accepted into the program. **Please review the Submission Guidelines for additional information.**

CONTACT US

If you have any questions, **please email us at arcs@arcs.com.au**

Conference Themes

- Clinical research operations
- Data, technology and informatics in clinical research
- Leadership, wellness & resilience
- Manufacturing
- Medical device regulation
- Medical devices reimbursement
- Medical information/Medical affairs
- Medicine reimbursement
- Non-prescription medicine regulation
- Prescription medicines regulation
- Pharmacovigilance
- Small and Medium Enterprises (SME) support

Submission Guidelines

1. Submission formats

The ACPC encourages submissions which are thought provoking and include the sharing of actual case studies to promote information exchange and knowledge sharing.

Abstracts may be submitted for the following:

- **Information session:** 60 minute didactic session on a relevant topic and attendee engagement
- **Forum sessions** 60 minute concept designed for panel interaction and attendee engagement (limited use of PowerPoint)
- **Workshop session**: 60 minute concept geared towards interactive/simulation or a role-playing format
- **Individual presentation**: 20-30 minute speaking slot (including Q&A) addressing a specific topic

There are three formats for sessions:

Information An information session is delivered lecture-style from the podium. The submitter acts as session chair to coordinate efforts in recruiting speakers and manage the session (including the facilitation of question and answers from the audience). PowerPoint presentations are required. Maximum of two speakers per session.

Workshop A workshop is designed for hands-on learning with a focus on application. The abstract submitter is considered the workshop chair and ensures the workshop provides learning in the form of activities or demonstrations, including handouts (accessed via the conference app). Maximum of two speakers per session.

Forum A forum is designed for panel interaction and attendee engagement. The submitter acts as forum chair, recruiting panel members and ensuring good representation/diversity in their selection. PowerPoint use is strongly discouraged by panelists. Maximum of four panel members per session.

Individual presentation is:

Speaking slot A speaking slot is a presentation covering a specific topic area, and the abstract submitter is also the speaker. For accepted speaking slots, submissions will be allocated to a session with another aligned topic. We will identify a chair who will introduce the speaker (you) and the topic, mange time and facilitate Q&A.

Submission Guidelines

2. General instructions for submitters (or authors)

- Submissions should reflect contemporary, new and evolving areas of work practices, policy and/or approaches.
- Submissions for sessions should include diverse perspectives from a range of organisations.
- Submission which includes a patient or health consumer perspective are encouraged.
- Each session must include all the required information contained within the submission planning form including full details of the speakers (full name, position, affiliation, email). Incomplete abstracts may not be assessed during the initial consideration (round one offers) of the ACPC.
- Submissions will be included into the program by the ACPC based on educational need, relevance to the ARCS membership, content and general fit within the program.
- ARCS Australia reserves the right to accept, reject or change submissions (including speaker suggestions) at its sole discretion.
- All submissions must adhere to the ARCS policy prohibiting explicit promotion of products or services by session speakers or chairs.

3. Sessions involving a TGA speaker(s)

ARCS Australia has a formal process for requesting TGA speakers for the conference. The ACPC kindly requests that individuals do not contact the TGA directly in regard to speaking at the conference. Instead, please include the details of the speaker and the specific topic(s) you would like covered (e.g., "Someone from the medical device authorisation branch (such as Joe Blogs) able to speak on the latest update to..."). Feedback from past conferences is that attendees value it when a substantial portion of the session involving TGA is dedicated to Q&A. The ACPC is calling for submissions from individuals able to provide an industry perspective (e.g., contribute as a speaker/chair).

Any request for a TGA speaker(s) must be accompanied by a full abstract and the full names of any non-TGA speakers (full name, position, affiliation, email). All requests for TGA speakers are submitted to TGA for consideration with a final decision anticipated by the end of February 2023. Please have a contingency in place if TGA declines participation in your session.

Submission Guidelines

4. Engaging your audience

The ACPC encourages submissions which balance content delivery and audience involvement. The conference will have polling capability which allows you to "ask the audience", check understanding on presented case studies, prioritise topics for a panel or introduce a game to keep people engaged. If you like these ideas and/or have other interactive ideas for your proposed session(s) or presentation(s) please add these as part of your submission. The ARCS team is here to help you through this process!

5. Making a submission

1. Submissions must be made in accordance with these Submission Guidelines.
2. Download and complete the submission planning form. This will help ensure that you have all the required information available before making your submission.
3. Review the process for including a TGA speaker in your session (if applicable).
4. For sessions (information, forum and workshop), forward the completed submission planning form to your speakers to get input and agreement to speak.
5. Each session and speaking slot submission must include all the required information contained within the submission planning form including full details of the speakers (full name, affiliation, role, email). Incomplete submissions may not be assessed during the initial consideration (round one offers) of the ACPC.
6. Make your submissions via the online portal by the designated deadline.

You are invited to make submissions in accordance with the Submission Guidelines via the following submission portals

- Individual presentations (speaking slot) portal
- Session (information, forum, workshop) portal

Submission Guidelines

6. The role of the chair

The chair is critically important to the success of the session. The chair's role is to manage the development and delivery of the session by:

- Developing the topic and session outline
- Identifying and making contact with the speakers. Share the learning objectives with potential speakers
- Uploading the proposal to the online portal
- Adding confirmed speakers to the session via the online portal
- Keeping the proposal updated via the online portal
- Ensuring the speakers are familiar with the ARCS policy "Explicit promotion of products or services from the podium" (see section 11)
- Working with all speakers as a team to develop the session and deliver on time
- Reviewing presentations for length, relevance and to avoid duplication between speakers
- Managing the session "on the day"

The 2023 ARCS Annual Conference is an in-person conference. Where the chair is based outside of Sydney, ARCS strongly recommends a Sydney-based back-up be identified who will act as a local host during the session in the event of COVID related travel restrictions. The host's role is to act as the "eyes and ears" in the room.

7. Chair reward and recognition

Chairs will receive a complimentary registration for the day of chairing (which does not include access to the conference dinner). ARCS does not cover travel related costs of chairs. ARCS will provide a discount on registration for chairs who would like to attend sessions on their non-chairing day(s).

Chairs who contribute significantly and meet the timelines outlined in these submission guidelines will received complimentary registration to attend one non-chairing day(s). The additional complimentary day registration is not transferable. ARCS at its sole discretion reserves the right to make determinations on chair rewards and recognition.

Submission Guidelines

8. Speaking at the conference

The 2023 ARCS Annual Conference is an in-person event with speakers and panellist presenting in person. Provision for remote participation has been made for international speakers only. In the event of travel restrictions due to COVID, virtual participation (live or pre-recorded) will be possible for speakers based outside Sydney.

7. Speaker reward and recognition

ARCS Australia is a not-for-profit professional development association which relies greatly on the voluntary services of our members and non-members associated with the health industry to develop and deliver our conference program. As such ARCS does not pay honoraria for speakers at conference sessions. ARCS is pleased to organise and cover costs of domestic travel for approved speakers (best available travel to be determined and organised by the ARCS office). If the speaker chooses to organise their own travel, ARCS will reimburse up to a specified amount.

For those speakers from commercial organisations, ARCS would welcome their support by covering their own travel related costs. Please contact us at arcs@arcs.com.au if you have a question.

ARCS will also provide complimentary conference registration for the day on which speakers are contributing (this does not extend to the conference dinner). If speakers would like to attend another day(s) of the conference, ARCS is pleased to offer a discount to attend the non-speaking day(s).

10. Panel members reward recognition

For approved forum sessions, ARCS Australia will cover costs of domestic travel for two panel members and provide complimentary conference registration for all panel members on the day on which they are contributing (this does not extend to the conference dinner).

Submission Guidelines

11. Explicit promotion of products or services from the Podium

ARCS appreciates the contribution made by all speakers at ARCS events. In order to maintain the integrity of the educational content, all speakers at ARCS events, whether members or not, are expected to limit their presentation to the technical, scientific or procedural topic under discussion.

Speakers from organisations and institutions which provide services or products must not overtly endorse or recommend a product or service during the course of the presentation. The content of slides, handouts and other presentation aids should not promote a commercial product or service.

12. Sponsored session (exhibition hall)

ARCS Australia offers exhibitors and sponsors the opportunity to promote products and services as sponsored sessions. These sessions are conducted in the exhibition hall and are separated from the educational sessions (and are identified accordingly). These sessions are not reviewed by the ACPC. Please refer to the 2023 ARCS Annual Conference exhibition and sponsorship prospectus or contact ARCS Australia at arcs@arcs.com.au if you are interested in learning more able our sponsored session offering at the conference.

13. Planning dates for the diary

Call for abstracts close	28 Oct 2022
Submitters notified of outcome	5 Dec to 16 Dec
Speaker requirements due (including biography, photo, travel requirements, permissions)	10 Feb 2023
Presentations & polls	31 May 2023

ARCS Australia reserves the right at its sole discretion to update the information contained within these guidelines.

APPENDIX A. Themes and priority areas

The following are only provided as a guide and are not exhaustive. Both, topics listed here and others submitted by the due date, will be reviewed and considered by the ACPC.

2. Clinical research operations

Topics of interest are welcome from industry in both interventional and non-interventional research and topics of interest include, but not limited to:

- Innovation in protocol and trial design to enable flexibility in times of continuous change
- Key international and local clinical research updates
- Non-clinical and early phase clinical trials
- Indigenous health
- Site management – feasibility, selection, budgets and contracts
- Regulation and guideline updates and their impact on clinical research
- Clinical collaborations
- Monitoring trends
- Quality compliance and risk management - audit (practices and outcomes)
- HREC/Governance – innovation, current trends, state/jurisdictional differences, compliance and oversight of clinical trials
- Patient engagement
- Registries
- Resourcing and skilling of the clinical research workforce

APPENDIX A. Themes and priority areas

Data, technology and informatics in clinical research

Topics of interest are welcome from industry in both interventional and non-interventional research and topics of interest include, but not limited to:

- Regulation and guideline updates and their impact on data management
- Clinical trial innovation (COA, ePROs, apps, VR, AI, AR, mobile technology, wearables, telemedicine, EMR, portals, software, hardware etc.)
- Clinical research involving IVDs, digital medical devices & diagnostics
- Social media and clinical trials
- Digital medicine and digital therapeutics
- Emerging technology and clinical trials including, EDC, eConsent, eSignature, CTMS, eTMFs, EMR, AI, block chain including validation and audit of these systems
- Detection and prevention of fraud and misconduct in clinical trials
- Analytics and big data – recruitment, clinical evidence, connectivity
- The impact of change in trial conduct (RBM, decentralised trials) on data management
- Preparing the workforce for technology integration

APPENDIX A. Themes and priority areas

Self-leadership, wellbeing & resilience

This stream is composed of sessions addressing topics and issues relating to self-leadership, wellbeing & resilience.

2. Topics of interest include, but not limited to:

- Managing and leading in a post-COVID world
- Creating work-life balance
- Self-regulation & awareness
- The ability to inspire and convince others
- Strategic thinking skills
- The ability to turn information into action
- Active listening
- Influence
- Flexibility
- Project planning
- Building trust
- Time management
- Communication skills
- Persuasion skills
- Increasing resilience & mindfulness
- Cultivating positive emotions
- Mental agility and flexibility; and
- Decision making

APPENDIX A. Themes and priority areas

Manufacturing

Topics should relate to manufacturing and quality management best practices from a manufacturer (local or overseas) and an Australian sponsor perspective. Topics of interest include, but not limited to:

2.

- GMP inspection trends inspection reliance
- Remote GMP inspections
- GMP clearances (including managing the backlog)
- Update on PIC/S guide to GMP for medicinal products version 14
- GMP compliance for listed medicines
- GMP implementation of TGOs 92 and 101
- GMP requirements in emerging areas such custom medical devices, gene therapy, genomic editing, cell therapy and tissue engineering & regenerative medicine
- GMP licence applications
- Manufacturing investigational medicinal products
- Management of GMP compliance signals
- implications of complex global supply chains

APPENDIX A. Themes and priority areas

Medical affairs

This stream is composed of sessions addressing topics and issues relating to those working in a medical affairs role, but not limited to:

2.

- Up skilling in therapeutic area knowledge
- Scientific meeting planning
- Managing the KOL relationship
- Creating synergy between marketing and medical affairs
- Metrics and the medical affairs value proposition
- Building scientific awareness
- Initiating and maintaining relationships with healthcare customers
- Compliance with legal and regulatory guidelines
- Gathering and providing competitive intelligence

APPENDIX A. Themes and priority areas

Medical device regulation

This stream is composed of sessions addressing laws, regulations, guidelines and classification rules that govern medical device approval and maintenance. Sessions may focus on implementation, approaches, insights, updates including (but not limited to):

- Reforms to IVDs (companion diagnostics, self-tests)
- Local alignment with EU MDR
- New clinical evidence guidance for medical devices
- Impact of the repeal of conformity assessments
- Post market monitoring and surveillance
- Medical device patient information leaflets and implant cards
- Unique Device Identification (UDI)
- Software as a Medical Device (SaMD)
- Custom made medical devices & Medical Device Production Systems (MDPS)
- Australian conformity assessment bodies (AU CABS)
- Comparable overseas regulators
- MDSAP experiences
- Regulatory changes impacting Australian regulatory requirements (in particular, comparable overseas regulators, ASEAN, Japan, Korea and China)
- Conformity assessment in emerging areas (such as SaMD & PMD & MDPS)
- Challenges/approaches to regulatory changes through the supply chain

APPENDIX A. Themes and priority areas

Medical device reimbursement

This interest area focuses on current issues related to the generation, analysis, and utilisation of evidence to assess the impact of medical technology products on health outcomes. Topics of interest include, but are not limited to:

2.

- Impact of the new MASC guidelines
- Update on the MASC cost recovery process
- Prostheses list reforms
- The patient voice in health technology assessment
- Funding pathways for digital healthcare (including use of digital health formularies)
- Value-based healthcare
- Real world evidence (including registers)
- Health technology assessment in emerging areas such custom medical devices, machine leaning assisted software and robotic surgery

APPENDIX A. Themes and priority areas

Medical information

Topics related to the practice and provision of drug or medical information for internal or external customers including healthcare professional and consumers. Topics of interest include, but are not limited to:

- Legal and regulatory developments impacting medical information (including privacy & information security, code of conduct)
- Healthcare professional and patient engagement (including HCP & consumer engagement, scientific exchange, awareness of medical information services)
- External partnerships (including public health initiatives, collaboration with professional societies)
- Outsourcing, third party management and vendor oversight
- Technology in medical information (including search engine optimisation, artificial intelligence and natural language processing, digital channels
- Medical information professional development (including customer facing skills, contact centre management, medical writing, multifunctional collaboration

APPENDIX A. Themes and priority areas

Medicine reimbursement

This stream is composed of sessions addressing the generation, analysis, and utilisation of evidence to assess the impact of medicines on health outcomes. Sessions may focus on implementation, approaches, insights, updates including (but not limited to)::

2.

- Health technology analysis (HTA) review including
  - How uncertainty is shared and managed, speed to access, ICER thresholds and discount rates
  - HTA assessment processes (including horizon scanning, conditional listing arrangements, repurposing of medicines, and lowest cost comparator)
- How the PBAC assesses value for money? What is the value of life and quality of life?
- The patient voice in HTA (and the use of lived experience)
- Post-PBAC processes including
  - Special pricing arrangements, risk sharing arrangements, price certainty, post market review framework, new therapeutic groups and rapid post-market reviews)
- Funding pathways for digital healthcare (including use of digital health formularies)
- Funding pathways for Advanced Therapy Medicinal Products (ATMPs) including gene therapy, genomic editing, cell therapy and tissue engineering & regenerative medicine
- The access gap generated by the new TGA regulatory accelerated approval pathways
- The broader societal effects of medicines and technology on society
- Resourcing and skilling of the HTA workforce

APPENDIX A. Themes and priority areas

Non-prescription medicines regulation (OTC and complementary medicines)

This stream is composed of sessions addressing laws, regulations, and guidances that govern non-prescription medicine approval, and maintenance. Sessions may focus on challenges, issues, approaches, strategies and updates including (but not limited to):

2.

- Cannabidiol based products (Schedule 3) pathways
- New assessed listed medicines (Aust L(A) pathway)
- Permitted indications for listed medicines
- TGA assessed claim
- Evidence guidance restructure and update
- Enhance supply chain resilience (& Australian manufacturing)
- Down scheduling/SUSMP application
- Digital health and the non-prescription medicine sector
- Review of the therapeutic goods advertising code
- Reforms for applications for new ingredients for listed medicines
- Mandatory requirements for new ingredients applications
- Post-market compliance reviews

APPENDIX A. Themes and priority areas

Prescription medicine regulation

This stream is composed of sessions addressing laws, regulations, and guidelines that govern prescription medicine approval, and maintenance. Sessions may focus on challenges, issues, approaches, strategies and updates including (but not limited to):

- Transitioning from provisional approvals to full applications
- Labelling orders TG091/92 process
- Practical insights in registering medicines with Health Canada, Health Sciences Authority, Singapore, Swissmedic and MHPRA
- Impact of BREXIT on the comparator overseas pathways
- Application of the reliance pathways (including priority and provisional pathways, COR-A and COR-B, ACCESS work-sharing & Project Orbit)
- TGA/PBAC submission interface (joint clinical evaluation)
- Use of Real-World Evidence (RWE) & PROs in regulatory applications
- Rare diseases and repurposing of medicines & orphan drug pathways
- TGA digital transformation project
- CMC changes and post-approval protocol (ICH Q12)
- New Zealand regulatory update (including legislative reforms, digital transformation, work sharing plans, resourcing)
- The patient voice in regulatory decision making
- Global supply chain management
- Medicine's shortages information initiative & mandatory reporting
- Generics & biosimilars development

APPENDIX A. Themes and priority areas

Pharmacovigilance

This stream is composed of sessions addressing laws, regulations, and guidances that govern the detection, assessment, understanding and prevention of adverse effects of medicine and vaccines. Sessions may focus on challenges, issues, approaches, strategies and updates including (but not limited to):

- New regulatory requirements and expectations regarding drug safety
- Pharmacovigilance audits/inspections
- Managing remote audits and inspections
- Significant safety issues (including application of the new guidelines)
- Benefit-risk assessment and management (including additional risk minimisation measures)
- Safety considerations with combination products
- Safety considerations with Advanced Therapy Medicinal Products (ATMPs) including gene therapy, genomic editing, cell therapy and tissue engineering & regenerative medicine
- Application of artificial intelligence to pharmacovigilance
- Good pharmacovigilance practices
- Product safety and new data sources (including social media)
- Signal detection and management across the product lifecycle.
- Pharmacovigilance in clinical trials/special access/ Investigator initiated trials
- Pharmacovigilance and advanced therapeutic techniques
- The future of pharmacovigilance (changing role of the pharmacovigilance professional)
- New drug applications from a pharmacovigilance perspective

APPENDIX A. Themes and priority areas

Small and Medium Enterprises (SME) support

2.

Proposals on topics of interest for start-ups (founders), SMEs (leaders with responsibilities for appointing clinical trial partners and or strategic development), commercialisation executives & clinicians and researchers. The purpose of these sessions are informational, roundtables, storytelling and awareness building for new entries into the SME space. Topics of interest include but not limited to:

- Investor communication
- Commercial judgment
- Opportunity and unmet need identification
- Intellectual property strategy and management
- Who is the customer & positioning the technology or product.
- The disconnect between early-stage development and commercialisation
- Business and commercialisation development plan
- Market analysis (local and global)
- Stakeholder management
- Regulatory requirements (local and global)
- Funding models (who will pay)
- Strategic partnerships
- Translational understanding
- Project planning and management
- Budget development and management

ARCS Australia reserves the right at its sole discretion to update the information contained within these guidelines.

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